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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/603,214	06/25/2003	Frank C. Barker	USAV2001/0077US NP	4330

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ROSS J. OEHLER
AVENTIS PHARMACEUTICALS INC.
ROUTE 202-206
MAIL CODE: D303A
BRIDGEWATER, NJ 08807

EXAMINER

FOSTER, JIMMY G

ART UNIT	PAPER NUMBER
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3728

DATE MAILED: 06/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/603,214

Applicant(s)

BARKER, FRANK C.

Examiner

Jimmy G. Foster

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-108 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 65-83 is/are allowed.
- 6) ☒ Claim(s) 1-8, 14-28, 32-64, 84-99 and 103-108 is/are rejected.
- 7) ☒ Claim(s) 9-13, 29-31 and 100-102 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>11/17/03</u> . | 6) <input type="checkbox"/> Other: ____. |

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1) Claims 65-83 are allowable. The reference of Garrill et al (6,179,118 B1) does not disclose the combination of HFA propellant impermeability for a package and an absorbent material in the package for absorbing HFA propellant. In fact, the reference, and all of the other references with respect to the packaging of HFA pressurized containers in sealable packaging teach away from impermeability of the package with respect to the HFA propellant. The intention of the references is to permit escape of the HFA propellant instead of letting it build up in the package.

2) 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3) Claims 33-64 are rejected under 35 U.S.C. 101 as being to non-statutory subject matter for patenting. The claims are to the use of a package and fail to define a method with any method steps. The statute 35 U.S.C. 101 does not provide for patenting the use of something.

4) The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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5) Claims 1-8, 14, 19, 26-28, 32-40, 46, 51, 58, 59, 61 and 64 are rejected under 35 U.S.C. § 102(b) as being anticipated by Garrill et al (6,179,118 B1).

The reference of Garrill et al discloses a moisture absorbent in a package that stores a pressurized metered dose inhaler. However, one of the variety of moisture absorbents listed by the reference is an activated bentonite clay. Applicant has disclosed that activated bentonite clay will function as an absorbent for hydrofluoroalkane propellants, such as HFA 134a and HFA 227. Accordingly, the activated bentonite clay disclosed by Garrill et al will also absorb such propellants.

The mere discovery of a new use of an old device will not support patentability. The mere discovery that bentonite clay will also absorb propellants will therefore not support patentability.

The reference discloses a package 22, a pressurized inhaler 36, an HFA 134a or HFA 227 propellant in the inhaler along with a drug, such as an antihistamine, and the activated bentonite absorbent material 50 in the package with the inhaler. The package, which is a plastic bag, is heat sealed. The package is permeable with respect to the propellant. According to the disclosure, the drug formulation may include excipients and may include surfactants, although the reference tends to indicate that they may not be necessary.

The package is made of a polyester outer layer, an aluminum foil middle layer and a heat sealable polyethylene inner layer.

6) The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if

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the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7) Claims 15-18, 20-25, 47-50, 52-57, 84-99 and 103-108 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Garrill et al (6,179,118 B1).

Although the reference of Garrill et al does not disclose the amount of permeability to HFA propellants, the reference discloses the general condition of being permeable to such propellants. It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. To have provided the package of Garrill et al with any workable range of values of permeability to the HFA propellants would therefore have been obvious as being merely to the discovery, and employment, of a desired or workable range of values of permeability.

Another general condition in the Garrill et al is the absorbency of HFA propellants, an inherent property of activated bentonite clay (disclosed by the reference) which the reference identifies with moisture absorbency. Accordingly to have discovered a workable range of values of absorbance of HFA propellants, including the rates of absorbency claimed by Applicant, would have been obvious since discovery of a workable range of a general condition already within the prior art would have been obvious (as stated above). Moreover to have provided any amount of the bentonite clay for any desired amount of moisture absorbency would have been obvious in view of the general condition that is recognized by the reference with respect to moisture absorbency.

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8) Claims 9-11 and 100-102 are objected to as being dependent on a rejected claim, but would be allowable if amended to include all of the limitations of the base claim and any intervening claim. While the reference of Garrill et al does disclose molecular sieves, the reference does not disclose a particular pore size for HFA propellants. Therefore the pore size of 10 Angstroms would not have been obvious in view of Garrill et al.

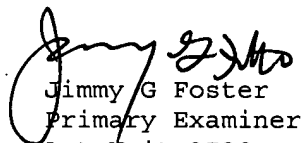
Claims 12, 13 and 29-31 are objected to as being dependent on a rejected claim, but would be allowable if amended to include all of the limitations of the base claim and any intervening claim. The reference of Garrill et al (6,179,118 B1) does not disclose the combination of HFA propellant impermeability for a package and an absorbent material in the package for absorbing HFA propellant. In fact the reference, and all of the other references with respect to the packaging of HFA pressurized containers in sealable packaging teach away from impermeability of the package with respect to the HFA propellant. The intention of the references is to permit escape of the HFA propellant instead of letting it build up in the package.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jimmy G. Foster whose telephone number is (571) 272-4554. The examiner can normally be reached on Mon-Fri, 8:45 am - 5:15 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mickey Yu can be reached on (571) 272-4562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Jimmy G Foster
Primary Examiner
Art Unit 3728

JGF

23 June 2005